

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACURA PHARMACEUTICALS, INC.,)
)
Plaintiff,)
)
v.) C.A. No. 12-1373-RGA
)
SANDOZ INC.)
)
Defendant.)
)

**DEFENDANT SANDOZ INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND
COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT**

Defendant Sandoz Inc. ("Sandoz") hereby submits this Answer, Affirmative Defenses, and Counterclaims ("Answer") to the Complaint filed by Acura Pharmaceuticals, Inc. ("Acura"). Except as expressly admitted below, Sandoz denies each and every allegation of the Complaint.

JURISDICTION AND PARTIES

1. On information and belief, Sandoz admits that Acura is a New York corporation having its principal place of business at 616 N. North Court, Suite 120, Palatine, Illinois 60067. Except as expressly admitted, Sandoz is without sufficient knowledge or information to form a belief about the truth of the remaining allegations contained in paragraph 1 of the Complaint, and on that basis denies each and every one of them.

2. Sandoz admits that it is a corporation organized and existing under the laws of the State of Colorado, having its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540. Sandoz agrees not to contest personal jurisdiction for purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case

as to any party, including Acura Pharmaceuticals, Inc. Except as expressly admitted, Sandoz denies the remaining allegations contained in paragraph 2 of the Complaint.

3. Paragraph 3 of the Complaint contains legal conclusions and requires no response. To the extent that paragraph 3 contains any factual allegations, Sandoz, except as expressly admitted, denies the allegations contained therein. Sandoz agrees not to contest personal jurisdiction for purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Acura Pharmaceuticals, Inc.

4. Sandoz admits that the Delaware Board of Pharmacy issued Sandoz a “Pharmacy-Wholesale” license and a “Distributor/Manufacturer CSR” license. Sandoz agrees not to contest personal jurisdiction for purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Acura Pharmaceuticals, Inc. Except as expressly admitted, Sandoz denies the remaining allegations contained in paragraph 4 of the Complaint.

5. Sandoz admits that it has indirectly derived revenue from sales of pharmaceutical products in Delaware. Except as expressly admitted, Sandoz denies the remaining allegations contained in paragraph 5 of the Complaint.

6. Sandoz agrees not to contest personal jurisdiction for purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Acura Pharmaceuticals, Inc. Except as expressly admitted, Sandoz denies the remaining allegations contained in paragraph 6 of the Complaint.

7. Paragraph 7 of the Complaint contains legal conclusions and requires no response. Sandoz admits that this action purports to be an action arising under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2). Sandoz admits that this Court

has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Sandoz denies that venue is proper but agrees not to contest venue for purposes of this action only. Except as expressly admitted, Sandoz denies the remaining allegations contained in paragraph 7 of the Complaint.

COUNT I FOR PATENT INFRINGEMENT
(Infringement of the '726 Patent under 35 U.S.C. § 271(e)(2))

8. Sandoz incorporates by reference the responses stated in paragraphs 1-7 of this Answer.

9. Sandoz admits that the '726 patent is entitled "Methods and Compositions for Deterring Abuse of Opioid Containing Dosage Forms" and, on its face, has an issue date of March 31, 2009. Sandoz denies that the '726 patent was duly and legally issued by the United States Patent and Trademark Office ("Patent Office"). Sandoz admits that Exhibit A to the Complaint appears to be a copy of the '726 patent and admits that Exhibit B to the Complaint appears to be a copy of a terminal disclaimer. Except as expressly admitted, Sandoz is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations contained in paragraph 9 of the Complaint, and on that basis denies each and every one of them.

10. Sandoz admits that the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") lists the '726 patent as associated with New Drug Application ("NDA") No. 20-2080. Except as expressly admitted, Sandoz is without sufficient knowledge or information to form a belief about the truth of the remaining allegations contained in paragraph 10 of the Complaint, and on that basis denies each and every one of them.

11. Sandoz admits that it submitted Abbreviated New Drug Application ("ANDA") No. 20-4155 ("Sandoz's ANDA") to the U.S. Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355(j) for oxycodone hydrochloride tablets in 5 mg and 7.5 mg dosage strengths

(the “Sandoz Products”). Except as expressly admitted, Sandoz denies the remaining allegations contained in paragraph 11 of the Complaint.

12. Sandoz admits that ANDA No. 20-4155 contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a “Paragraph IV Certification”) stating that the ’726 patent is “invalid or will not be infringed by the manufacture, use, or sale” of the Sandoz Products. Except as expressly admitted, Sandoz denies the remaining allegations contained in paragraph 12 of the Complaint.

13. Sandoz admits that in a letter dated October 1, 2012, Sandoz notified Plaintiff that Sandoz had submitted ANDA No. 20-4155 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j). Except as expressly admitted, Sandoz denies the remaining allegations contained in paragraph 13 of the Complaint.

14. Paragraph 14 of the Complaint contains legal conclusions and requires no response. To the extent that paragraph 14 contains any factual allegations, Sandoz admits that under 35 U.S.C. § 271(e)(2), the submission of an ANDA under 21 U.S.C. § 355(j) is a basis for invoking this Court’s subject matter jurisdiction. Except as expressly admitted, Sandoz denies the remaining allegations contained in paragraph 14 of the Complaint.

15. Paragraph 15 of the Complaint contains legal conclusions and requires no response. To the extent that paragraph 15 contains any factual allegations, Sandoz, except as expressly admitted, denies each and every allegation contained therein.

16. Sandoz denies the allegations contained in paragraph 16 of the Complaint.

COUNT II FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the
'726 Patent under 35 U.S.C. § 271(a) and/or (b))

17. Sandoz incorporates by reference the responses stated in paragraphs 1-16 of the Answer as if fully set forth herein.

18. Paragraph 18 of the Complaint contains legal conclusions and requires no response. To the extent that paragraph 18 contains any factual allegations, Sandoz admits that this claim purports to be a claim for declaratory judgment for patent infringement, arising under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271, and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202.

19. Sandoz admits that it submitted ANDA No. 20-4155 to the FDA pursuant to 21 U.S.C. § 355(j) for oxycodone hydrochloride tablets in 5 mg and 7.5 mg dosage strengths. Except as expressly admitted, Sandoz denies the remaining allegations contained in paragraph 19 of the Complaint.

20. Sandoz admits that it intends to sell the Sandoz Products in the United States after FDA approval of Sandoz's ANDA No. 20-4155. Except as expressly admitted, Sandoz denies the remaining allegations contained in paragraph 20 of the Complaint.

21. Sandoz admits that it was aware of the '726 patent to the extent that it referred to the '726 patent in the Sandoz ANDA. Except as expressly admitted, Sandoz denies the remaining allegations contained in paragraph 21 of the Complaint.

22. Sandoz admits that there is a justiciable controversy between Acura and Sandoz regarding non-infringement of the '726 patent. Except as expressly admitted, Sandoz denies the remaining allegations contained in paragraph 22 of the Complaint.

Prayer for Relief

Sandoz denies that Plaintiff is entitled to any of the relief requested in its Prayer for Relief.

AFFIRMATIVE DEFENSES

Without admitting or implying that Sandoz bears the burden of proof as to any of them, Sandoz, on information and belief, asserts the following affirmative defenses:

FIRST AFFIRMATIVE DEFENSE
(Non-infringement of the '726 Patent)

Sandoz and the Sandoz Products have not infringed, are not infringing, and will not infringe any valid and enforceable claim of the '726 patent directly or indirectly, either literally or by the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of the '726 Patent)

The '726 patent and each of the claims thereof are invalid for failure to comply with one of more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

THIRD AFFIRMATIVE DEFENSE
(Failure to State a Claim)

The Complaint fails to state a claim upon which relief can be granted.

COUNTERCLAIMS

Defendant and Counterclaimant Sandoz Inc. ("Sandoz") hereby submits these Counterclaims against Acura Pharmaceuticals, Inc. ("Acura"):

1. Sandoz repeats and incorporates by reference each of the foregoing paragraphs of Sandoz's Answer and Affirmative Defenses to the Complaint.

PARTIES

2. On information and belief, Acura is a New York corporation having its principal place of business at 616 N. North Court, Suite 120, Palatine, Illinois 60067.

3. Sandoz Inc. is a Colorado corporation with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

JURISDICTION AND VENUE

4. These Counterclaims arise under the Patents Laws of the United States, 35 U.S.C. § 100 *et seq.* This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and/or 2202.

5. This Court has personal jurisdiction over Acura because Acura has subjected itself to the jurisdiction of this Court by filing the Complaint and by filing complaints in related actions, including C.A. Nos. 12-01371-RGA, 12 -01372-RGA, and 12-01374-RGA, all of which concern at least U.S. Patent No. 7,510,726 (“the ’726 patent”).

6. Venue as to these Counterclaims is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

7. On information and belief, the United States Patent and Trademark Office (“Patent Office”), on March 31, 2009, issued the ’726 patent, entitled “Methods and Compositions for Deterring Abuse of Opioid Containing Dosage Forms.” On its face, the ’726 patent names Acura as the assignee. On information and belief, Acura purports to have all rights, title, and interest in this patent. A copy of the ’726 patent is attached hereto as Exhibit A.

8. On information and belief, the Patent Office, on April 10, 2007, issued U.S. Patent No. 7,201,920 (the “’920 patent”), entitled “Methods and Compositions for Deterring

Abuse of Opioid Containing Dosage Forms.” On its face, the ’920 patent names Acura as the assignee. On information and belief, Acura purports to have all rights, title, and interest in this patent. A copy of the ’920 patent is attached hereto as Exhibit B.

9. On information and belief, the Patent Office, on July 19, 2011, issued U.S. Patent No. 7,981,439 (the “’439 patent”), entitled “Methods and Compositions for Deterring Abuse of Drugs Susceptible to Abuse and Dosage Forms Thereof.” On its face, the ’439 patent names Acura as the assignee. On information and belief, Acura purports to have all rights, title, and interest in this patent. A copy of the ’439 patent is attached hereto as Exhibit C.

10. The Hatch-Waxman Amendments to the Food, Drug, and Cosmetic Act require New Drug Application (“NDA”) holders to disclose to the U.S. Food and Drug Administration (“FDA”) the patent numbers and expiration dates of those patents that the holder believes claim the “drug” for which their NDA is submitted, or patents covering a “method of using such drug.” 21 U.S.C. §§ 355(b)(1) and (c)(2).

11. On information and belief, Acura licensed the ’726 patent, the ’920 patent, and the ’439 patent to King Pharmaceuticals Research and Development, Inc. (“King”). On January 31, 2011, King was acquired by Pfizer Inc. (“Pfizer”) (collectively with King, “King/Pfizer”). On information and belief, King/Pfizer listed or caused to be listed the ’726 patent, the ’920 patent, and the ’439 patent in the *Approved Drug Products with Therapeutic Equivalence Evaluation* (“Orange Book”) in connection with NDA No. 20-2080.

12. Sandoz submitted Abbreviated New Drug Application (“ANDA”) No. 20-4155 (the “Sandoz ANDA” or “Sandoz’s ANDA”) to the FDA seeking approval to manufacture, use, and sell oxycodone hydrochloride tablets in 5 mg and 7.5 mg dosage strengths (the “Sandoz Products”).

13. The Sandoz ANDA included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a “Paragraph IV Certification”) stating that the ’726 patent, the ’920 patent, and the ’439 patent are invalid and/or will not be infringed by the manufacture, use, or sale of the Sandoz Products.

14. In separate letters dated October 1, 2012, Sandoz provided Acura, King, and Pfizer with a Notice of Certification under 21 U.S.C. § 355(j)(2)(B) for the Sandoz Products (the “Sandoz Notice Letters”), indicating that Sandoz had submitted ANDA No. 20-4155 and providing a detailed statement of the factual and legal basis of Sandoz’s Paragraph IV Certification. The Sandoz Notice Letters included an offer of confidential access pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

15. On October 31, 2012, Acura filed suit against Sandoz in this District, asserting that upon FDA approval of ANDA No. 20-4155, Sandoz’s commercial manufacture, use, sale, or offer to sell in, or importation into the United States of the Sandoz Products would infringe the ’726 patent.

16. To date, neither Acura nor King/Pfizer has filed any action alleging that the filing of the Sandoz ANDA infringes any claim of the ’920 patent or ’439 patent.

17. More than 45 days have elapsed since Sandoz provided notice of the filing of the Sandoz ANDA to Acura, King, and Pfizer.

18. Based on Acura’s pending allegations against Sandoz involving the ’726 patent and Sandoz’s intent to launch the Sandoz Products as soon as legally permissible, an actual and justiciable controversy exists between Acura and Sandoz regarding the non-infringement and invalidity of the ’726 patent, the ’920 patent, and the ’439 patent.

FIRST COUNTERCLAIM
(Declaratory Judgment of Non-infringement of the '726 Patent)

19. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and in paragraphs 1 through 18 of these Counterclaims above.

20. Sandoz and the Sandoz Products have not infringed, are not infringing, and will not infringe any valid and enforceable claim of the '726 patent directly or indirectly, either literally or by the doctrine of equivalents.

21. There exists an actual controversy between Sandoz and Acura regarding whether Sandoz infringes any valid claim of the '726 patent, and a judicial declaration of non-infringement is necessary and appropriate at this time.

SECOND COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '726 Patent)

22. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and 1 through 21 of these Counterclaims above.

23. The '726 patent and each of the claims thereof are invalid for failure to comply with one of more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

24. There exists an actual controversy between Sandoz and Acura regarding the validity of the '726 patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

THIRD COUNTERCLAIM
(Declaratory Judgment of Non-infringement of the '920 Patent)

25. Sandoz hereby incorporates by reference each and every allegation set forth in its

Answer and Affirmative Defenses to the Complaint and in paragraphs 1 through 24 of these Counterclaims above.

26. Sandoz and the Sandoz Products have not infringed, are not infringing, and will not infringe any valid and enforceable claim of the '920 patent directly or indirectly, either literally or by the doctrine of equivalents.

27. There exists an actual controversy between Sandoz and Acura regarding whether Sandoz infringes any valid claim of the '920 patent, and a judicial declaration of non-infringement is necessary and appropriate at this time.

FOURTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '920 Patent)

28. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and 1 through 27 of these Counterclaims above.

29. The '920 patent and each of the claims thereof are invalid for failure to comply with one of more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

30. There exists an actual controversy between Sandoz and Acura regarding the validity of the '920 patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

FIFTH COUNTERCLAIM
(Declaratory Judgment of Non-infringement of the '439 Patent)

31. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and in paragraphs 1 through 30 of these Counterclaims above.

32. Sandoz and the Sandoz Products have not infringed, are not infringing, and will not infringe any valid and enforceable claim of the '439 patent directly or indirectly, either literally or by the doctrine of equivalents.

33. There exists an actual controversy between Sandoz and Acura regarding whether Sandoz infringes any valid claim of the '439 patent, and a judicial declaration of non-infringement is necessary and appropriate at this time.

SIXTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '439 Patent)

34. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and 1 through 33 of these Counterclaims above.

35. The '439 patent and each of the claims thereof are invalid for failure to comply with one of more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

36. There exists an actual controversy between Sandoz and Acura regarding the validity of the '439 patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

PRAYER FOR RELIEF

WHEREFORE, Sandoz prays that the Court enter judgment in its favor and against Acura as follows:

1. Adjudging that Sandoz has not and will not infringe any patent asserted by Acura;
2. Adjudging that no patent asserted by Acura is valid;
3. Enjoining Acura and its agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof from threatening or

initiating infringement litigation against Sandoz or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Sandoz, or charging them either orally or in writing with infringement of any patent asserted herein against Sandoz;

4. Granting Sandoz judgment in its favor on the Complaint;
5. Denying Acura's request for injunctive relief;
6. Dismissing the Complaint with prejudice;
7. Declaring that the claims of the '726 patent, '920 patent, and '439 patent are invalid;
8. Declaring that the claims of the '726 patent, '920 patent, and '439 patent are not and will not be infringed by Sandoz;
9. Finding this case to be exceptional under 35 U.S.C. § 285 and awarding Sandoz its costs and reasonable attorneys' fees; and
10. Awarding any other such relief as is just and proper.

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Dated: January 10, 2013

CERTIFICATE OF SERVICE

I, Karen E. Keller, hereby certify that on January 10, 2013, this document was served on the persons listed below in the manner indicated:

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